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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,063	01/28/2002	Norihito Shimono	2002-0055A	8747

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,063	SHIMONO ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/31/06 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 21-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al Lerner et al (USPN 5,840,332 hereafter '332). The claims are drawn to a solid product comprising a core, first layer comprising a water-insoluble polymer having chitosan dispersed therein, and an enteric coating.

5. The '332 patent discloses a solid formulation comprising a core and successive coatings (abstract). The coating composition comprises a water-insoluble carrier with a particulate dispersed therein (col. 9, lin. 38-65). The particulate matter is chitosan, and the water-insoluble include well known such as various Eudragit polymers along with ethylcellulose (*Ibid.*). The

form further comprises an enteric coating (claim 4). The enteric coating comprises well-known enteric polymers including those based on methacrylic acid and methyl methacrylate copolymer (claim 17). The dosage form comes as a tablet, or pill, or capsule (abstract), and is designed for colonic delivery (col. 6, lin. 57-65). The reference teaches method of producing the coatings including dispersing the solid particulates in the water-insoluble polymer and coating a core pellet (examples).

6. Regarding claims 21-32, it is the position of the Examiner that these claims represent product-by-process claims, and as such patentable weight is not given to their process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

7. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983).

8. As discussed above the '332 reference discloses a solid formulation comprising a core with a successive coating of a water insoluble polymer with chitosan dispersed therein. The reference is silent however to the specific ratio of the particulate matter to that of the water-insoluble polymer. The reference teaches that this ratio is important in order to control the rate of the release of the drug (col. 11, lin. 50-55). The reference discloses several ratios however. Where the particulate matter and the polymer are in concentration 3:7, 7:3 and 1:1 (Figures 1-5). Theses ratios are proportional to those of the instant claims. However, it is the position of the Examiner that such a feature would be well within the level of skill in the art to determine through routine experimentation. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

9. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

10. With these things in mind it would be well within the level of skill in the art to follow the teachings and suggestions of '332 in order to produce a solid colonic dosage form. The artisan of ordinary skill would have been motivated to follow these teachings and disclosures with an expected result of a solid formulation useful for colic sustained delivery of active agents.

Response to Amendment

11. The Declaration filed under 37 CFR 1.132 filed 7/31/06 is insufficient to overcome the rejection of claims 21-40 based upon USC 103(a) as set forth in the last Office action because: the declaration is not commensurate with the scope of the claims. The claims recite three separate water insoluble polymers while the declaration only test for one (Eudragit RS). The declaration draws claims to drawn direct comparison between Examples 3,4,5 and 7 from the Lerner reference, yet has no recitation of the thickness of the polymer coating, a major factor in the rate of the release of the active agent as taught by the prior art. Further no other ratios (3:7 or 1:1) of the chitosan/Eudragit combination of the instant claims are tested. The ratio of insoluble particle: polymer is another major factor in testing the release rate, yet Applicant ignores it. Also the claims recite a range of ratios 1:4-4:1, yet the Declaration on reports on 7 discreet points. For these reasons at least the Declaration is insufficient to overcome the rejection.

Response to Arguments

12. Applicant's arguments filed 7/31/06 have been fully considered but they are not persuasive. Applicant argues that:

a. Based on the Declaration the Lerner reference does not obviate the claims

b. There is no motivation to follow the Lerner reference.

13. Regarding these arguments, it is the position of the Examiner that the Declaration fails to properly compare the prior art to the instant claims. As discussed above the Declaration fails to compare similar ratios or chitosan to the water insoluble polymers recited in the prior art. Applicant points to Experiment 1 as evidence of a distinction. However Experiment 1 is not an

adequate representation since not all ratios of the Lerner reference are represented (3:7 and 1:1 insoluble particle to water insoluble polymer) by the declaration. It has never been the assertion of the Examiner that calcium pactinate would replace the chitosan, but rather that the selection of a particular particle would be within the level of skill in the art. It is the position of the Examiner that choosing the chitosan as described by the prior art would be within the realm of routine experimentation. Further no proportional comparisons were made between the instant invention and the Lerner reference. Also the declaration was silent to the thickness of the polymer shell. Each example compared in the declaration reported 3 separate shell thicknesses, yet Applicant is silent to which thickness was tested. As Lerner states, 5 parameters control the release of an active agent: (1) size of the particulate matter; (2) thickness of the coating; (3) type of material forming the particulate matter; (4) ratio of particulate matter; and (5) water-insoluble film forming material. The Declaration only dealt with 3 of the 5 factors and remained silent to the remaining 2. It is the position of the Examiner that through routine experimentation an artisan of ordinary skill would be motivated to apply the chitosan recited in the Lerner reference into the coating in order adjust the release of the active agent.

14. The instant claims recite a preparation comprising a coating comprising chitosan and a water-insoluble polymer in a particular ratio. The Lerner reference discloses a preparation comprising a coating comprising chitosan, and water insoluble polymers in a particular ratio. The ratio proportionally falls within the scope of the claims along with the choice of chitosan. For these reasons the claims remain obviated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER